(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 831 751 B1

(12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:
06.11.2002 Bulletin 2002/45

(21) Application number: **96917215.4**

(22) Date of filing: **06.06.1996**

(51) Int Cl.7: **A61F 2/00**

(86) International application number:
PCT/US96/09032

(87) International publication number:
WO 96/039991 (19.12.1996 Gazette 1996/55)

(54) URETHRAL CAP

HARNRÖHRENKAPPE

CAPUCHON URETRAL

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI LU MC NL PT SE

(30) Priority: **07.06.1995 US 476092**
02.11.1995 US 556766

(43) Date of publication of application:
01.04.1998 Bulletin 1998/14

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EP 0 831 751 B1

Printed by Jouve, 75001 PARIS (FR)

Description

Background of the Invention

[0001] Urinary incontinence, such as stress incontinence, in females is a substantial problem throughout the world. A variety of mechanisms have been suggested for use to alleviate the condition, which can be a social as well as a medical problem, to those afflicted with the problem.

[0002] Many suggested medical devices to alleviate urinary incontinence in females require the use of internal components, such as catheters, balloons, pessaries or the like, which pass into the urethra, and are positioned within the body in use. Such internal components can be a source of irritation to the body and, in some cases, can result in infection or other unwanted body reactions. Moreover, such devices as are known can be expensive and/or inconvenient to use and transport for use.

[0003] GB-A-2193438 describes a urethral cap comprising a resilient, and at least partially-deformable, body defining a chamber therewithin, as well as an encircling flange having a body-contacting surface which acts as a sealing surface.

Summary of the Invention

[0004] It is an aim of this invention to provide a urethral cap for alleviating urinary incontinence, such as stress incontinence in females, which cap is inexpensive to provide, is simple to apply and remove, and which does not create a high risk of body infection.

[0005] Another aim of this invention is to provide a urethral cap in accordance with the preceding cap which utilises atmospheric pressure to maintain the cap in position on the body of a user.

[0006] Still another aim of the present invention is to provide a urethral cap in accordance with the preceding objects which can incorporate a sealing material which can be a lubricant or adhesive to aid attachment to the body.

[0007] Still another aim of the present invention is to provide a urethral cap usable in a method of alleviating urinary incontinency in a user by applying this urethral cap blocking the outer orifice of the urethra at the meatus, and utilising an air pressure difference to maintain the cap on the body of a user.

[0008] Still another aim of this invention is to provide a urethral cap usable in a method in accordance with the preceding method, wherein an adhesive is used in conjunction with holding the cap on the body.

[0009] Still another aim of this invention is to provide a urethral cap usable in a method in accordance with the preceding aims which can be rapidly carried out by a user, and provides safe and certain protection against incontinency in women.

[0010] The present invention provides a urethral cap for alleviating urinary incontinence when applied over the meatus of the body of a user, the cap comprising a resilient, at least partially-deformable cap body having a hand gripping portion, the cap body defining a chamber therewithin sized to allow for reciprocal resilient deformation of the cap body to provide a vacuum therein to hold the urethral cap on the body of the user, and to close the meatus of the body of the user, the chamber defining a central axis passing from the top of the cap to the bottom of the cap, the cap body defining, at its bottom, an encircling flange having a body-contacting surface to act as a sealing surface with the body of the user, thereby closing the meatus of the user by compression, wherein the cap carries a sealing material over the body-contacting surface for aiding in preventing liquid flow between the body-contacting surface and the body of the user when the cap is in use, characterised in that the cap provides a generally frustoconical inner surface adjacent to the body-contacting surface to aid in closing the meatus by compression.

[0011] Preferably, the encircling flange has a diameter of substantially 3 centimetres, and preferably in the range of substantially 2.4 to 3.3 centimetres, to allow proper positioning on the female body at the orifice of the urethra. Preferably, the cap is formed of a resilient body-compatible rubbery material such as silicone rubber, and can be sterilised and packaged under sterile conditions.

[0012] By using the invention, urinary incontinence in women is alleviated and unwanted urinary flow prevented by applying a urethral cap having an internal chamber, over a urethra outer body orifice of the user. The cap defines a hand-gripping portion and an encircling flange having a body-contacting surface which aids in sealing the urethral cap to the body of the user. Air pressure is employed below atmospheric air pressure to maintain the cap in place, and to compress the meatus. The urethral cap is removed to allow voiding when desired, and can be re-applied.

[0013] It is a feature of this invention that the chance of infection and internal irritation to a user is reduced, since no components of the cap pass into, or through, the urethra of the user, and the cap is external to the body. The cap can be made of standard non-irritating body-compatible materials such as silicone rubbers and the like. In use, the air pressure difference between the chamber of the cap and the atmosphere holds the cap in place. This positioning can be enhanced by use of an adhesive sealing material if desired, and/or is preferably enhanced by the use of a non-adhesive sealing material. The sealing material can be pre-applied. The cap allows for collection of a small amount of urine in an internal chamber, as well as ease of removal to allow urinary flow and ease of replacement. In ordinary use, the meatus is closed by the urethral cap, and no urine leakage occurs to the chamber or outside of the body. The cap can be made relatively inexpensively of inexpensive materials in proper sizing as required. A small number

of sizes can be used to fit the vast majority of users.

Brief Description of the Drawings

[0014] The above and other objects, features and advantages of the present invention will be better understood from the following description when read in conjunction with the accompanying drawings, in which:

FIG. 1 is a top view of a preferred embodiment of the urethral cap in accordance with this invention;
FIG. 2 is a cross-sectional view thereof taken through line 2-2 Of FIG. 1;
FIG. 3 is a bottom view thereof;
FIG. 4 is a cross-sectional view through a section of the flange of a cap in accordance with FIG. 1 having a plurality of sealing layers applied thereto;
FIG. 5 is a semi-diagrammatic top plan view of the urethral cap of FIG. 1 in place on the body of the user; and
FIG. 6 is a diagrammatic cross-sectional view as through line 2-2 of FIG. 1 of the urethral cap when in place on the body of the user.

Detailed Description

[0015] A preferred embodiment of a urethral cap or incontinence device is illustrated at 10 as best shown in FIGS. 1-3. The cap comprises a body 11 defining an inner chamber 12 with an outer flange 13 and an intermediate frustoconical portion 14.

[0016] The body of the urethral cap in the preferred embodiment of FIG. 1 has a cylindrical wall 15 around a central axis 40 of the cap, with a rounded outer end wall 16, a finger gripping ledge 17 and a body contacting encircling surface 18 are provided.

[0017] The urethral cap is preferably integrally formed as by conventional molding but can be made by dipping, spraying or other techniques. The material of the integral cap is preferably an FDA approved medical grade silicone rubber. However, elastomeric materials such as medical grade silicone rubber sold by Dow Corning Co., elastomeric urethanes, polyvinyl chlorides, natural and other rubbery material or synthetic polymeric materials can be used. In some cases, the body need not be integrally formed but can be formed of rigid materials which can be polymeric or metallic. In these cases, at least a portion of the body opening into the interior chamber 12 is formed of a resilient material which can be elastically and reciprocally moved by the fingers from the at rest position as shown in FIG. 2 to a compressed or reduced chamber position and then allowed to expand to the at rest position. This is necessary in order to provide at least a partial vacuum in the chamber to seal the cap to the body by an air pressure differential between the air within the chamber and the atmospheric air pressure as will be described.

[0018] The side wall thickness of the cap is arranged so that side wall 15 has a thicker section and is more resistant to collapse or deformation by atmospheric pressure than is the flange portion 13 which tapers from the wall 15. The thickness of wall 15 can be, for example, 1.75 millimeter thick with a preferred range of 1.5 to 2.5 millimeter, with a flange 13 thickness I of, for example, 0.75 millimeter in the preferred embodiment and a preferred range of 0.5 to 1.5 millimeter and can be formed of an FDA approved medical grade silicone rubber. This difference in wall thickness prevents collapse on itself of the device in use, yet, allows for movement of the flange towards the body in use.

[0019] As best seen in the cross section of FIG. 6, the flange 13 can be deformed towards or closely contact the body at the planar area of the body surrounding the meatus or urethra orifice. A portion of orifice of the urethra indicated at 20 can be drawn into contact with the flange 13 and the frustoconical portion 14 which acts to close the meatus in order to maintain position of the cap, to form a good seal with the body at flange 13 and to close the meatus to urine flow.

[0020] In use, the meatus is preferably closed by a gentle compression of the area around the meatus to form a closure maintained in position by an air pressure difference. Any structure that provides a closure of the meatus to urine flow, yet allows comfort in use and ease of reuse, can provide the advantages of this invention. These advantages can be obtained by the device 10 acting solely externally of the body without any part thereof entering the body of a user.

[0021] The end wall 16 of the cap preferably provides a hand gripping wall 17 although any configuration which allows for finger gripping of the cap to allow positioning on the body and removal therefrom by the fingers of the user is acceptable. Thus, although the cap is shown as a cylindrical side wall, rounded end wall top with frustoconical section 14 and encircling flange 13, the shape can vary greatly. The section 14 is important to provide the closure of the meatus. Generally, the angle of the interim wall surface 141 with the surface 18 is obtuse to enhance closure of the meatus. This internal wall surface 141 is a lower portion of chamber 12 and closes the meatus by pressure thereof.

[0022] It is preferred that the flange 13 provide a body contacting surface 18 forming a continuous ring about the opening or meatus of the urethra of the body. However, other portions of the cap can be square, round, oblong, bulbous, or of any shape desired. Flat, rather than rounded end wall 16 can be used. In all cases, sufficient interior space is provided at the inner chamber 12 which extends to the tip of the flange, to provide for forming an at least partial vacuum in the chamber by finger compression, and allowing resilient rebound to the positioning as in FIG. 6.

[0023] The dimensions of the urethral cap can vary greatly.

[0024] However, consistent with normal anatomy of females in the United States, it is preferred that the di-

ameter A be in the range of 2.3 to 3.4 centimeters and more preferably 2.4 to 3.3 centimeters with 3 centimeters being used in the preferred embodiment. Where the flange 13 is oval or of other encircling shapes such as square, oblong, triangular or the like, the maximum flange width corresponding to the diameter of flange 13 between the labia is about 3.4 centimeters. Diameter B is preferably in the range of 1 centimeter to 2.5 centimeters with 1.5 millimeters being preferred. The height D of the device is preferably 1 to 3 centimeters and in the preferred embodiment 2 centimeters. This height can vary greatly but by maintaining the device approximately 1 to 3 centimeters in height, the device can be worn without discomfort, positioned easily and is resistant to dislodging by garments worn by the user.

[0025] Distance E can be, for example, 1.35 centimeters in the preferred embodiment with the chamber diameter of chamber 12 shown at F being 75 millimeters in the preferred embodiment. Distance H which defines in part the interior chamber can be 5.25 millimeters in the preferred embodiment but again can vary greatly. The most important dimensions relate to the range of 2.3 to 3.4 centimeters in outer diameter of flange 13 for proper positioning in the body and preferably the height is no more than about 3 centimeters to allow ease of use and 'reuse.

[0026] In the preferred embodiment, Silastic HS-30, manufactured by Dow-Corning Corp. of Midland, Michigan, is used as the elastomeric material for the integral cap 10. The Silastic HS-30 preferably has a Durometer Shore A of 32, tensile strength psi (Mpa) 1325(9.13) and an elongation of 1020%. The Silastic silicone rubber can be cured with conventional peroxide curing agents such as Lupersol 101, a product of Penwalt Corp. of Buffalo, New York. Conventional colorants can be used to add color as, for example, organic and inorganic pigments.

[0027] In use, a sealant material which can be an adhesive but need not be an adhesive, is applied to the body contacting surface 18. The purpose of this material shown in FIG. 4 at 30 is to provide an air and liquid seal between the skin of the body and the flange. If the seal is adhesive, it not only seals against air and liquid pressure leakage, but can also act to hold the device in contact with the body. However, it is preferred not to use solely an adhesive as the body adhering portion since this could be irritating to the body if sufficient adhesive is used to provide proper protection. On the other hand, when substantially no adhesive properties are used in the sealing material, sufficient protection against urinary leakage is provided by the incontinence device 10 of this invention.

[0028] The cap preferably is symmetrical about a central axis 40 shown in FIGS. 2 and 3 although it need not be symmetrical in all embodiments.

[0029] The sealing material 30 can be known adhesives which are nonirritating to the body and can be used in contact with the body over a period of time. Such adhesives include the water soluble paste FIXADENT® or CONFIDENT an adhesive produced by Block Drug of Jersey City, New Jersey. However, sealing materials such as conventional lubricants including petrolatum or petroleum jelly such as Vaseline® can be used without adhesive properties. The sealing material such as petroleum jelly compensates for irregularities in the skin or cap sealing surface flange and thus provides for protection against air and urine leakage in use of the device when the device is applied to the body.

[0030] The sealing material 30 can be applied by the user using a Q-tip applicator or the fingertip to rub the vaseline or adhesive over the body sealing surface just prior to use. In some cases, the lubricant or adhesive can be prepositioned on the device with a cover or release strip 31 applied thereover to prevent sticking or removal of the sealant or adhesive prior to application. In some cases, a plurality of sealant and cover strips can be used as suggested in FIG. 4 at 32 and 33. Thus, in the first application, the lower strip 33 is removed exposing an underlying surface 32 of adhesive or lubricant sealing material for a first application to the body. This can be done where the sealant directly contacting the flange directly is an adhesive and, thus, the product is maintained on the body. After first removal, the second cover strip 31 can be removed to expose the underlying adhesive 30 for a second application. Any number of protective strips and sealant layers can be used as desired. In the preferred embodiment, the sealant material is applied just prior to use by the user as when vaseline petroleum jelly is used.

[0031] FIGS. 5 and 6 diagrammatically show placement on the body. In FIG. 5, the labia 41 are diagrammatically illustrated with the urethral opening or meatus 42 being shown with the flange 13 positioned thereover. In FIG. 6, the cap 10 is shown in position with the skin of the body about the meatus pulled into direct contact with the body contacting surface 18 of the flange and the underside of the frustoconical portion 14. This closes the urethral orifice and the positioning of the skin below the flange acts to aid in centering and maintaining the cap in position on the body as well as to prevent urine outflow. Similarly, because the flange 13 is positioned to lie substantially just within the labia 41 at a planar area around the meatus, positioning is maintained and this spacing aids in locating and placing the urethral cap in position.

[0032] In the method of applying the urethral cap of this invention, the cap is deformed inwardly by the fingers of the user and then applied to the orifice of the urethra and allowed to expand to its original shape as shown in FIG. 2. This creates a vacuum within the inner chamber 12 causing outside atmospheric pressure to push against the flange 13 and frustoconical portion 14 and maintain the urethral cap in good sealing engagement with the body. The skin or tissue immediately surrounding the meatus is compressed by the air pressure difference and a seal is formed with the cap 10 at the surface 141. The sealing material pre-applied to the

body-contacting surface aids in maintaining the seal. The pressure differential between the inside of the cap and the atmosphere can vary greatly. This depends in part on atmospheric conditions, as well as how much depression is applied to the chamber before it resiliently returns to its normal position shown in Figure 2. In some cases, the full repositioning of Figure 2 is not achieved after compression of the side wall in application, but in all cases, some chamber vacuum or partial vacuum remains inside the cap. The interior chamber 12 can act as a reservoir if there is some leakage while the cap is in place, although this does not normally occur.

[0033] As previously noted, the skirt size is such that it aids in positioning the skirt in proper position over the urethral orifice, and also maintaining the cap in place. The finger grip is important for placement particularly in older patients. The finger grip can be simply the cylindrical outer surface of chamber 12.

[0034] The differential in air pressure between the inside of the cap and the atmosphere is difficult to determine. In many cases, the air pressure differential may be as little as 6900 Pa (1 psi), or can be 13800-34500 Pa (2-5 psi) or 41400-690000 Pa (6-10 psi) or more. Preferably, the pressure is applied by the depression of the cap and the expansion thereof towards its original shape since the walls are resiliently deformable. This can result in different amounts of pressure when even the same cap is used depending on how it is applied and how much depression occurs. Surprisingly, it has been found that, even with small caps, following the method of this invention, sufficient air pressure difference is obtained to maintain the cap in position and avoid urine flow.

[0035] Thus, a user can alleviate urinary incontinence such as stress incontinence by applying the cap over the urethral orifice using the labia spacing to help position the cap. Prior to contact with the body, the cap is resiliently depressed at the hand gripping portion and the encircling flange is brought into contact with the skin surrounding the orifice opening. The body contacting portion of the flange has been previously treated with petroleum jelly or an adhesive as previously described. Slight pressure on the skin and release of the pressure deforming the cap causes a suction within the cap and provides the air pressure difference on the outside of the flange and frustoconical portion 14 that maintains the cap in place on the body and closes the meatus as shown in Fig. 6. The cap can be easily removed to allow voiding when desired. In some cases, the cap can merely be pulled off the skin although a slight depression of the finger gripping portion is desired to alleviate the pressure difference first. The device is comfortable in use, can be easily applied by a majority of patients and has been found to prevent urinary leakage and thus alleviate urinary incontinence in women, including stress urinary incontinence.

[0036] In the preferred embodiment, the cap is packaged in a surrounding clear plastic container or envelope diagrammatically illustrated at 50. This maintains the cleanliness of the cap prior to usage. Such envelopes are known in the art and can comprise thin plastic films which can be see through or opaque. Other conventional packages can be used to store and transport the urethral cap to maintain cleanliness. In some cases, a plurality of caps can be packaged in a single package or no package need be used. In some cases, the caps of this invention can be sterilized. Preferably, the caps 10 of this invention are manufactured and packaged under and meeting ISO 9000 standards to provide cleanliness, manufacturing quality and lot control. Thus, contamination, including bacterial contamination, is minimized.

[0037] The urinary caps of this invention can be sterilized to reduce the risk of infection or irritation to the skin. Sterilization is not required since the device is external to the body and does not have any component passing within the urethra.

[0038] It has been found that caps of this type are useful for long periods of time and maintain the contact with the skin in sealing arrangement for periods of 2 to 6 hours or more in some cases.

[0039] While specific embodiments of this invention have been shown and described, it will be obvious to those skilled in the art that many variations are possible. The particular materials, integral nature, geometric configuration of the devices of this invention can vary greatly. In all cases, a pressure differential is instrumental in providing a body contacting seal to alleviate conditions of incontinency which seal acts along with a mechanical closure of the meatus. The seal formed by the flange 13, portion 14 and the body by the air pressure difference between the chamber and atmosphere and the adhesive contact if used, is sufficiently strong to withstand and to prevent urinary flow out of the cap over long periods of time at urinary pressures normally encountered at the urethral orifice.

Claims

1. A urethral cap (10) for alleviating urinary incontinence when applied over the meatus of the body of a user, the cap comprising a resilient, at least partially-deformable cap body (11) having a hand gripping portion (17), the cap body defining a chamber (12) therewithin sized to allow for reciprocal resilient deformation of the cap body to provide a vacuum therein to hold the urethral cap on the body of the user, and to close the meatus of the body of the user, the chamber defining a central axis (40) passing from the top of the cap to the bottom of the cap, the cap body defining, at its bottom, an encircling flange (13) having a body-contacting surface (18) to act as a sealing surface with the body of the user, thereby closing the meatus of the user by compression, wherein the cap carries a sealing material (30) over

the body-contacting surface for aiding in preventing liquid flow between the body-contacting surface and the body of the user when the cap is in use, **characterised in that** the cap provides a generally frustoconical inner surface adjacent to the body-contacting surface to aid in closing the meatus by compression.

2. A urethral cap as claimed in claim 1, wherein the encircling flange (13) has an outer diameter of from substantially 2.3 to substantially 3.4 centimetres.

3. A urethral cap as claimed in claim 2, wherein the encircling flange (13) has an outer diameter of substantially 3 centimetres.

4. A urethral cap as claimed in any one of claims 1 to 3, wherein the bottom of the cap (10) is defined by the encircling flange (13), and the height of the cap from its top to its bottom is substantially 2 centimetres.

5. A urethral cap as claimed in any one of claims 1 to 4, wherein the cap (10) is integrally formed of a resilient material which allows ease of application to the body of the user by deforming the cap chamber (12), applying the cap to the body of the user about the orifice of a urethra, and releasing said deforming pressure to define an air pressure difference between the chamber (12) and the atmosphere sufficient to seal the flange (13) to the user, and to prevent liquid flow therethrough at normal pressures encountered in urinary fluids expressed by the body, the cap further defining a meatus-constricting surface to close the meatus when the cap is applied with said pressure difference acting to position the cap.

6. A urinary cap as claimed in any one of claims 1 to 5, wherein the cap (10) is formed of an FDA-approved silicone rubber.

7. A urinary cap as claimed in any one of claims 1 to 6, wherein the cap (10) carries a layer of the sealing material (30) over the body-contacting surface (18), and wherein a release strip (31) covers the sealing material.

8. A urethral cap as claimed in claim 7, further comprising a second layer of sealing material (32) over the release strip (31), and a second release strip (33) overlying the second layer of sealing material.

9. A urethral cap as claimed in any one of claims 1 to 8, wherein the sealing material (30) is a lubricant with no adhesive properties.

10. A urethral cap as claimed in any one claims 1 to 8, wherein the sealing material (30) is an adhesive.

11. A urethral cap as claimed in any one of clams 1 to 10, wherein the cap (10) conforms to ISO 9000 manufacturing standards.

12. A urethral cap as claimed in claim 11, wherein the cap (10) is packaged in accordance with ISO 9000 manufacturing standards.

13. A urethral cap as claimed in any one of claims 1 to 12, wherein the cap (10) is integrally formed of a silicone rubber material compatible with, and non-irritating to, the skin of the body of the user.

Patentansprüche

1. Harnröhrenkappe (10) zur Linderung von Harninkontinenz bei Anwendung über der Meatus des Körpers einer Benutzerin, umfassend einen elastischen, mindestens teilweise verformbaren Kappenkörper (11) mit einem Handgriffabschnitt (17), wobei der Kappenkörper eine Kammer (12) darin definiert, welche derart bemessen ist, dass sie eine elastische Hin- und Herverformung des Kappenkörpers ermöglicht, um ein Vakuum darin zum Halten der Harnröhrenkappe auf dem Körper der Benutzerin zu liefern, und zum Schließen der Meatus des Körpers der Benutzerin, wobei die Kammer eine Mittelachse (40) definiert, welche von der Oberseite der Kappe zur Unterseite der Kappe verläuft, wobei der Kappenkörper an der Unterseite davon einen umgebenden Flansch (13) mit einer Körperkontaktfläche (18) definiert, welche als Dichtungsfläche mit dem Körper der Benutzerin dient, wodurch der Meatus der Benutzerin geschlossen wird durch Kompression, wobei die Kappe ein Dichtungsmaterial (30) über der Körperkontaktfläche trägt, um ein Verhindern eines Flüssigkeitsflusses zwischen der Körperkontaktfläche und dem Körper der Benutzerin zu unterstützen, wenn die Kappe im Einsatz ist, **dadurch gekennzeichnet, dass** die Kappe eine generell kegelstumpfartige Innenfläche neben der Körperkontaktfläche aufweist, um ein Schließen der Meatus durch Kompression zu unterstützen.

2. Harnröhrenkappe nach Anspruch 1, wobei der umgebende Flansch (13) einen Außendurchmesser von im Wesentlichen 2,3 bis im Wesentlichen 3,4 cm aufweist.

3. Harnröhrenkappe nach Anspruch 2, wobei der umgebende Flansch (13) einen Außendurchmesser von im Wesentlichen 3 cm aufweist.

4. Harnröhrenkappe nach einem der Ansprüche 1 bis 3, wobei die Unterseite der Kappe (10) definiert ist

durch den umgebenden Flansch (13) und die Höhe der Kappe von deren Oberseite zu deren Unterseite im Wesentlichen 2 cm beträgt.

5. Harnröhrenkappe nach einem der Ansprüche 1 bis 4, wobei die Kappe (10) einstückig gebildet ist aus einem elastischen Material, welches eine einfache Anwendung auf den Körper der Benutzerin ermöglicht durch Verformen der Kappenkammer (12), Anwenden der Kappe auf den Körper der Benutzerin um die Öffnung einer Harnröhre und Lösen des Verformungsdrucks zum Definieren eines Luftdruckunterschieds zwischen der Kammer (12) und der Atmosphäre, welcher ausreicht, den Flansch (13) gegen die Benutzerin zu dichten und ein Durchfließen der Flüssigkeit bei Normaldrücken, welche in vom Körper abgegebenen Harnflüssigkeiten auftreten, zu verhindern, wobei die Kappe ferner eine den Meatus einengende Fläche zum Schließen des Meatus bei Anwendung der Kappe mit einem Druckunterschied, welcher zur Positionierung der Kappe dient, definiert.

6. Harnröhrenkappe nach einem der Ansprüche 1 bis 5, wobei die Kappe (10) aus einem FDA-zugelassenen Silikongummi besteht.

7. Harnröhrenkappe nach einem der Ansprüche 1 bis 6, wobei die Kappe (10) eine Schicht des Dichtungsmaterials (30) über der Körperkontaktfläche (18) trägt, und wobei der Lösestreifen (31) das Dichtungsmaterial bedeckt.

8. Harnröhrenkappe nach Anspruch 7, ferner umfassend eine zweite Schicht eines Dichtungsmaterials (32) über dem Lösestreifen (31) und einen zweiten Lösestreifen (33) über der zweiten Schicht des Dichtungsmaterials.

9. Harnröhrenkappe nach einem der Ansprüche 1 bis 8, wobei das Dichtungsmaterial (30) ein Schmiermittel ohne Hafteigenschaften ist.

10. Harnröhrenkappe nach einem der Anspräche 1 bis 8, wobei das Dichtungsmaterial (30) ein Haftmittel ist.

11. Harnröhrenkappe nach einem der Ansprüche 1 bis 10, wobei die Kappe (10) den ISO 9000 Herstellstandards entspricht.

12. Harnröhrenkappe nach Anspruch 11, wobei die Kappe (10) gemäß den ISO 9000 Herstellstandards verpackt ist.

13. Harnröhrenkappe nach einem der Ansprüche 1 bis 12, wobei die Kappe (10) einstückig gebildet ist aus einem Silikongummimaterial, welches für die Haut des Körpers der Benutzerin verträglich ist und diese nicht reizt.

Revendications

1. Capuchon urétral (10) pour soulager l'incontinence urinaire lorsqu'il est appliqué sur le méat du corps d'un utilisateur, le capuchon comprenant un corps de capuchon (11) élastique et au moins partiellement déformable présentant une partie de préhension manuelle (17), le corps de capuchon définissant une chambre (12) à l'intérieur de celui-ci dimensionnée pour permettre la déformation élastique réciproque du corps de capuchon afin d'établir un vide intérieur destiné à maintenir le capuchon urétral sur le corps de l'utilisateur et fermer le méat du corps de l'utilisateur, la chambre définissant un axe central (40) s'étendant du sommet du capuchon vers la partie inférieure du capuchon, le corps de capuchon définissant, au niveau de sa partie inférieure, un anneau de ceinturage (13) présentant une surface de contact corporel (18) destinée à agir en tant que surface d'étanchéité avec le corps de l'utilisateur, fermant ainsi le méat de l'utilisateur par compression, la surface du capuchon en contact avec le corps étant garnie d'une matière d'étanchéité (30) pour éviter encore plus l'écoulement de liquide entre la surface en contact avec le corps et le corps de l'utilisateur lorsque le capuchon est utilisé, **caractérisé en ce que** le capuchon forme une surface interne généralement tronconique adjacente à la surface en contact avec le corps pour assister la fermeture du méat par compression.

2. Capuchon urétral selon la revendication 1, **caractérisé en ce que** l'anneau de ceinturage (13) présente un diamètre externe compris sensiblement entre 2,3 et 3,4 centimètres.

3. Capuchon urétral selon la revendication 2, **caractérisé en ce que** l'anneau de ceinturage (13) présente un diamètre sensiblement égal à 3 centimètres.

4. Capuchon urétral selon l'une quelconque des revendications 1 à 3, **caractérisé en ce que** la partie inférieure du capuchon (10) est délimitée par l'anneau de ceinturage (13), et **en ce que** la hauteur du capuchon depuis son sommet jusqu'à sa partie inférieure est sensiblement égale à 2 centimètres.

5. Capuchon urétral selon l'une quelconque des revendications 1 à 4, **caractérisé en ce que** le capuchon (10) est formé d'une seule pièce en une matière élastique qui permet une application aisée sur le corps de l'utilisateur par déformation de la chambre (12) du capuchon, application du capuchon sur

le corps de l'utilisateur au niveau de l'orifice de l'urètre, et relâchement de la pression de déformation pour définir une différence de pression d'air entre la chambre (12) et l'atmosphère suffisante pour ajuster l'anneau de ceinturage (13) de manière étanche au corps de l'utilisateur, et pour empêcher l'écoulement de liquide à travers celui-ci à des pressions normales rencontrées pour des fluides urinaires évacués par le corps, le capuchon définissant en outre une surface de constriction du méat pour fermer le méat lorsque le capuchon est appliqué, la différence de pression agissant pour positionner le capuchon.

6. Capuchon urétral selon l'une quelconque des revendications 1 à 5, **caractérisé en ce que** le capuchon (10) est réalisé en un caoutchouc de silicone approuvé par la Food and Drug Administration (FDA).

7. Capuchon urétral selon l'une quelconque des revendications 1 à 6, **caractérisé en ce que** le capuchon (10) comporte une couche de matière d'étanchéité (30) sur la surface en contact avec le corps (18) et **en ce qu'**une pellicule détachable (31) recouvre la matière d'étanchéité.

8. Capuchon urétral selon la revendication 7, **caractérisé en ce qu'**il comporte en outre une seconde couche de matière d'étanchéité (32) sur la pellicule détachable (31), et une seconde pellicule détachable (33) recouvrant la seconde couche de matière d'étanchéité.

9. Capuchon urétral selon l'une quelconque des revendications 1 à 8, **caractérisé en ce que** la matière d'étanchéité (30) est un lubrifiant sans propriétés adhésives.

10. Capuchon urétral selon l'une quelconque des revendications 1 à 8, **caractérisé en ce que** la matière d'étanchéité (30) est un adhésif.

11. Capuchon urétral selon l'une quelconque des revendications 1 à 10, **caractérisé en ce que** le capuchon (10) est conforme à la norme de fabrication ISO 9000.

12. Capuchon urétral selon l'une quelconque des revendications 1 à 11, **caractérisé en ce que** le capuchon (10) est conditionné selon la norme de fabrication ISO 9000.

13. Capuchon urétral selon l'une quelconque des revendications 1 à 12, **caractérisé en ce que** le capuchon (10) est formé d'une seule pièce dans une matière en caoutchouc de silicone compatible avec, et non irritative pour, la peau du corps de l'utilisateur.

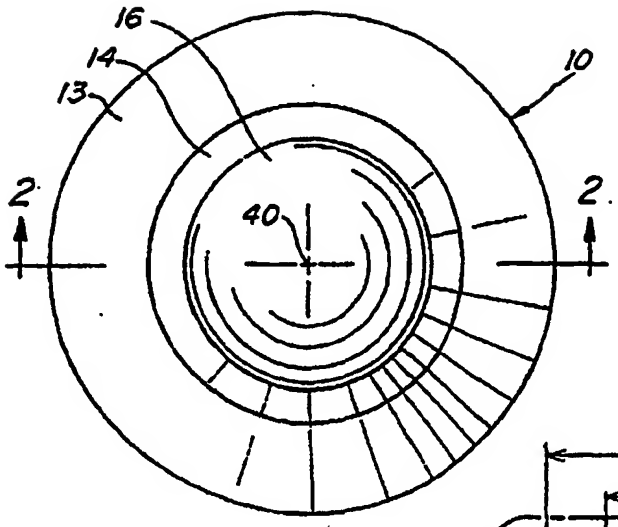

Fig. 1

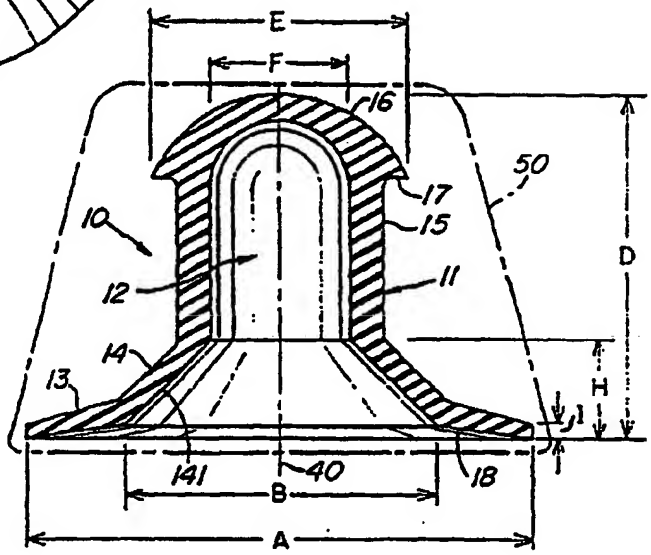

Fig. 2

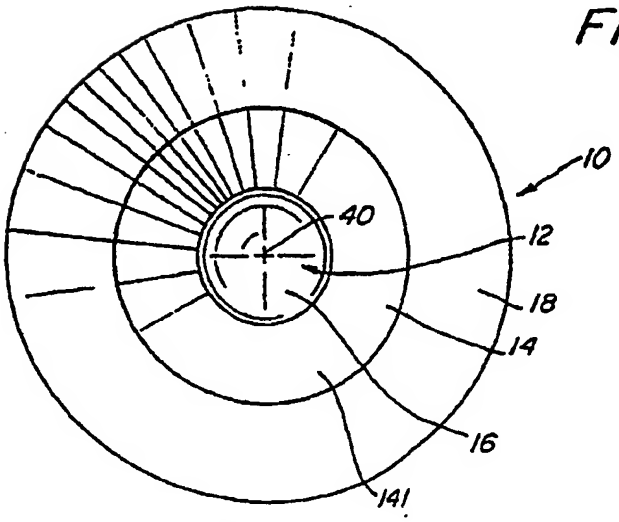

Fig. 3

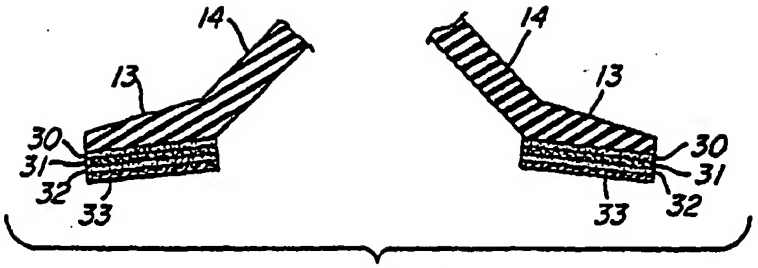

Fig. 4

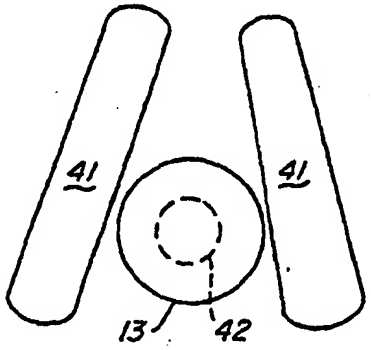

Fig. 5

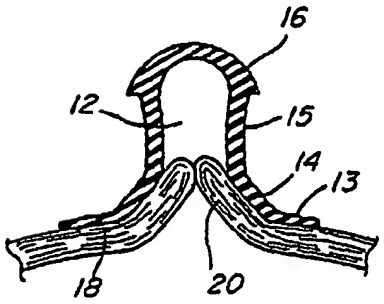

FIG. 6